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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,002	08/31/2001	Roy Duncan	78973-1C/pw	9961

7590 11/12/2004

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,002	DUNCAN, ROY	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-28 and 41-77* is/are pending in the application.

4a) Of the above claim(s) *7-28,41-56 and 58-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 4-28, 41-77 remain pending.

Applicants' election of Group 1 (claims 4-6 and 57) is acknowledged, as is the elected specie (SEQ ID No: 10). Although applicants have not traversed the restriction, applicants have argued that Groups 4, 6, 8 and 10 should be rejoined with Group 1 in the event that the latter is found to be allowable. Certainly, it would be appropriate to rejoin claims that are drawn to a method of making or using the proteins of Group 1 (if claims to such proteins are determined to be allowable). However, claim 18 is another matter. Claim 4 specifies that the protein be isolated; claim 18 specifies that the protein is not isolated. If a cell has been infected with a reovirus, it stands to reason that all proteins encoded by the virus would be expressed. Thus, if claims to an isolated protein are determined to be novel, it does not necessarily follow therefrom that claims to a complex mixture containing the isolated protein would also be novel. (However, novelty would likely accrue to claim 24, if claim 4 is novel).

Claims 4-6 and 57 are examined in this Office action; claims 7-28, 41-56, 58-77 are withdrawn from consideration.

✧

Claims 4-6 and 57 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 5 is drawn to SEQ ID NO: 14, which consists of 140 amino acid residues. Claim 4, upon which claim 5 is recited to be dependent, requires the molecular weight to be "about" 15 kD. However, the molecular weight of SEQ ID NO: 14 is well in excess of 15 kD. To achieve a molecular weight of 15 kD, the average molecular weight of the amino acid residues would have to be 107 g/mol. Of the genetically encoded amino acids only Ala, Val, Pro, Gly, Ser, Thr, and Cys have a molecular weight at or below 107 g/mol (subtracting out H_2O). Clearly, these amino acids do not dominate. Further, having a myristoyl group (210 g/mol) bonded to the peptide is going to add to the weight of the protein.

- Claim 4 recites the phrase "less than about", thus rendering the claim indefinite as to the upper limit of amino acids.

- Claim 4 recites the phrases "relatively small" intracellular domain, "relatively small" extracellular domain and "relatively" non-immunogenic, thus rendering the claim indefinite as to the criteria for "relatively small" and "relatively non-immunogenic".

- In claims 5-6, if the term "BRV" is going to be used, it should be accompanied by a definition of the term at issue (presumably baboon reovirus).

- Claim 57 is indefinite as to what may be encompassed by the term "membrane fusion" protein. The issue here is not that of preferred embodiments. Rather, the issue is that which is present at the "outer limits" of what this term might encompass. For example, suppose that one first prepares a phospholipid bilayer on a plate of class, and then prepares a second phospholipid bilayer in close proximity to the first. If the two "membranes" are mechanically mixed, would this constitute membrane fusion?

✧

Claim 4 is rejected under 35 U.S.C. §102 (b) as being anticipated by Subramanian (*Virus Genes* 15, 83, 1997) or Ernst (*Proc Natl Acad Sci* 82, 48, 1985).

Subramanian discloses a peptide obtained from a reovirus that has a molecular weight of 15.7 kD. Similarly, Ernst teaches a peptide obtained from a reovirus that has a molecular weight of 14 kD.

The recited properties are inherent; the claim is anticipated.

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 57 is rejected under 35 U.S.C. §103 as being unpatentable over Subramanian (*Virus Genes* 15, 83, 1997) in view of Schullery S E, *Biochemistry* **19**(17) 3919-23, 1980 or Lentz B. R. *Biochemistry* **26** (17) 5389-97, 1987 or Fonteijn T. A., *Biochemistry* **30** (21) 5319-24, 1991.

Subramanian discloses a peptide obtained from a reovirus that has a molecular weight of 15.7 kD. Subramanian does not disclose that this peptide fails to inhibit membrane fusion. Each of the secondary references discloses that liposomes can undergo spontaneous fusion. None of the secondary references discloses peptides encoded by reoviruses.

The issue raised by this rejection is that of the full scope and meaning of the term "membrane fusion protein" (abbreviated "MFP"). Presumably, one of the meanings of this term would be such that both of the following conditions must be met: (a) if two mammalian cells are placed in close proximity to one another, and in the presence of the MFP, fusion of the two cells will occur to form a single cell, and (b) if two mammalian cells are placed in close proximity to one another in the absence of the MFP, no detectable membrane fusion will occur. The issue, however, is that which is this term encompasses, and not merely preferred embodiments.

The term "membrane fusion protein" could be construed as encompassing any protein which permits membrane fusion to occur when it is present, while at the same time, not requiring membrane fusion to be absent when the protein is absent. As it happens, there are many situations in which membrane fusion occurs spontaneously. The secondary references provide examples of this occurring between phospholipid vesicles. The membrane specialist of ordinary skill would have expected that if a small amount of a protein such as that disclosed by

Subramanian were included in the phospholipid vesicle solution disclosed in the secondary references, membrane fusion would still occur, and that therefore the label "membrane fusion protein" could be applied to the protein which has been added. This is not to say, of course, that the protein will necessarily cause membrane fusion to occur in situations where it does not occur spontaneously; however, the claim does not require such.

Thus, the claim is rendered obvious.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600